

Attorney Docket No.: **DC0258US.NP**  
Inventors: **Supattapone and Deleault**  
Serial No.: **10/553,591**  
Filing Date: **January 17, 2006**  
Page 6

#### **REMARKS**

Claims 1-3 are pending in this application. Claim 2 has been withdrawn from consideration. Claims 1 and 3 have been rejected. Claims 1-3 have been canceled. Claims 4-5 have been added. The specification has been amended to correct an inadvertent typographical error at page 2. No new matter has been added by these amendments to the claims. Applicants are respectfully requesting reconsideration in light of the amendments to the claims and the following remarks.

#### **I. Election/Restriction Requirement Under 35 U.S.C. §121**

The restriction requirement placing the claims into Groups I-II has been deemed proper and made final. The Examiner suggests that because claim 1 does not recite an isolated preparation of a ribonucleic acid molecule, Applicants arguments filed April 7, 2008 are not commensurate in scope with the claimed invention. In light of this restriction requirement, claim 2 has been withdrawn from further consideration. Accordingly, Applicants have canceled claim 2 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

#### **II. Rejection of Claims Under 35 U.S.C. 101**

Claim 1 has been rejected under 35 U.S.C. 101 for being directed to non-statutory subject matter. It is suggested that claim 1 is directed to a naturally occurring composition of matter as demonstrated by Saborio ((2001) *Nature* 411:810-3). The Examiner suggests that the claim recites the composition in

Attorney Docket No.: **DC0258US.NP**  
Inventors: **Supattapone and Deleault**  
Serial No.: **10/553,591**  
Filing Date: **January 17, 2006**  
Page 7

"open" claim language and the ribonucleic acid molecule is not recited as "isolated" or "purified" with respect to its natural surroundings. Applicants disagree with this rejection. However, in the interest of clarifying the instant composition, Applicants have canceled claims 1 and 3 and added new claims 4 and 5, which indicate that the composition consists of isolated ribonucleic acid molecules which enhance the amplification of PrP<sup>Sc</sup>. Claims 4 and 5 are directly supported by the paragraph spanning pages 6 and 7, which describes experiments demonstrating that isolated RNA molecules can reconstitute the ability of benzonase-pretreated brain homogenate to amplify PrP<sup>Sc</sup> in a dose-dependent manner. In so far as Applicants have, by this amendment, distinguished the instant invention from a naturally occurring composition, it is respectfully requested that this rejection be withdrawn.

### **III. Rejection of Claims Under 35 U.S.C. 102**

Claim 1 has been rejected under 35 U.S.C. 102(b) as being anticipated by Saborio et al. It is suggested that this reference teaches *in vitro* amplification of PrP<sup>Sc</sup>, wherein the healthy hamster brain homogenate disclosed therein is suggested to necessarily contain a ribonucleic acid molecule that enhances the amplification of PrP<sup>Sc</sup>.

Applicants respectfully traverse this rejection. As disclosed in the paragraph spanning pages 6 and 7, and reflected in new claim 5, Applicants have demonstrated that isolated RNA molecules can reconstitute the ability of benzonase-pretreated brain homogenate to amplify PrP<sup>Sc</sup> in a dose-dependent manner.

Attorney Docket No.: **DC0258US.NP**  
Inventors: **Supattapone and Deleault**  
Serial No.: **10/553,591**  
Filing Date: **January 17, 2006**  
Page 8

While Saborio et al. teach total hamster brain homogenate, this reference does not teach or suggest isolated ribonucleic acid molecules for enhancing the amplification of PrP<sup>Sc</sup>.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP 2131.

In so far as Saborio et al. fail to teach each and every element of the claims as currently presented, this reference cannot be held to anticipate the present invention. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

#### **IV. Rejection of Claims Under 35 U.S.C. 102**

Claim 3 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Saborio et al. in view of Stratagene ((1988) Gene Characterization Kits). As discussed above, Saborio et al. are suggested to teach healthy hamster brain homogenate, which necessarily contains a ribonucleic acid molecule that enhances the amplification of PrP<sup>Sc</sup>. The Examiner acknowledges that Saborio et al. do not expressly teach kits of reagents; however, Stratagene is suggested to provide teachings that are supportive of a motivation to combine reagents into kit format. It is concluded that it would have been prima facie obvious to a skilled artisan at the time the invention was made to combine the reaction reagents as taught by Saborio et al. in to a kit format as discussed by Stratagene Catalog.

Attorney Docket No.: **DC0258US.NP**  
Inventors: **Supattapone and Deleault**  
Serial No.: **10/553,591**  
Filing Date: **January 17, 2006**  
Page 9

Applicants respectfully traverse this rejection. Under 35 U.S.C. §103, the factual inquiry into obviousness requires a determination of: (1) the scope and content of the prior art; (2) the differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

In the instant case, the primary reference does not teach each and every element of the invention as currently presented. In so far as the Stratagene Catalog merely discusses the use of kits, this reference fails to remedy the deficiencies of the primary reference. Accordingly, when combined, the teachings of the cited references fail to teach or suggest the subject matter of the claims as currently presented. Therefore, Saborio et al. in view of the Stratagene Catalog cannot be held to make the present invention obvious under 35 U.S.C. 103(a). It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

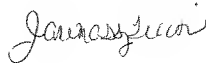
#### **V. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

Attorney Docket No.: **DC0258US.NP**  
Inventors: **Supattapone and Deleault**  
Serial No.: **10/553,591**  
Filing Date: **January 17, 2006**  
Page 10

favorable reconsideration and subsequent allowance of the  
pending claim is earnestly solicited.

Respectfully submitted,



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